



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/575,177

09/11/2007

David Butler

59752(70207)

7290

21874

7590

06/19/2009

EDWARDS ANGELL PALMER & DODGE LLP

P.O. BOX 55874

BOSTON, MA 02205

EXAMINER

BIANCHI, KRISTIN A

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

06/19/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/575,177 | Applicant(s) BUTLER ET AL. | |
| | Examiner KRISTIN BIANCHI | Art Unit 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 50-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7,8,11,16 and 50-52 is/are rejected.
- 7) ☒ Claim(s) 1-16 and 52 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/10/2006 and 02/22/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-16 and 50-52 are pending in the instant application. Claims 1-4, 7, 8, 11, 16, and 50-52 are rejected. Claims 1-16 and 52 are objected.

Information Disclosure Statements

The information disclosure statements filed on October 10, 2006 and February 22, 2007 have been considered and signed copies of form 1449 are enclosed herewith.

Election/Restrictions

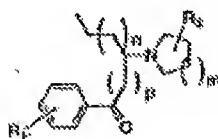
Applicant's election with traverse of the compound N-[4-(2-Pyrrolidin-1-yl-pentanoyl)-phenyl]-acetamide, hydrogen chloride salt in the response filed on April 6, 2009 has been acknowledged. The traversal is on the grounds: there is no undue burden. This not found to be persuasive because some of the formulae disclosed in claim 1 (i.e., see Office Action dated February 3, 2009) are independent and distinct from each other because there is no patentable co-action between the formulae and a reference anticipating a compound of one formula will not render a compound of a different formula obvious. Some of the formulae are directed to art recognized divergent subject matter which require different searching strategies for each formula. Moreover, the examiner must perform a commercial database search on compounds of each formula in addition to a paper search, which is quite burdensome to the examiner. Therefore, the requirement is still considered proper and is maintained.

The examiner will follow the guidelines of MPEP 803.02 wherein once a species is elected, it is examined for compliance with all applicable statutes for patentability and if compliance is found, then the examination is expanded to a reasonable number of

Art Unit: 1626

related species to determine whether they also comply with the statute. The examiner will determine whether the entire scope of the claims is patentable according to MPEP 803.02.

Applicant's elected species appears allowable over the prior art of record. Therefore, according to MPEP 803.02: should no prior art be found that anticipated or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is found that anticipated or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The search of the Markush-type claim has been extended to the non-elected species wherein:



the compounds are of the formula

wherein

m is 1;

n is 1;

p is 0; and

R1 and R3 are as defined in the instant claims.

As prior art has been found which anticipates the above identified nonelected species, the Markush-type claims are rejected as follows and the subject matter of the claims drawn to nonelected species held withdrawn from consideration. Claims 1-16 and 50-52 have been examined to the extent that they are readable on the elected embodiment and the above identified nonelected species. Since art was found on the

Art Unit: 1626

nonelected species, subject matter not embraced by the elected embodiment or the above identified nonelected species is therefore withdrawn from further consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, claim 2 does not provide a definition for the variable R2 and this makes the claim indefinite. Appropriate correction is required.

Specifically, claim 8 discloses that R' can be 4-C(O)O-alkyl. There is insufficient antecedent basis for this limitation in the claim because claim 2 (from which claim 8 depends) does not include 4-C(O)O-alkyl in the definition for R'. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 8, 11, 16, 50, and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Michaelis et al. (Journal of Medicinal Chemistry, 1970, Vol. 13, No. 3).

Specifically, Michaelis et al. discloses the compounds 1-(4-Hydroxymethylphenyl)-2-pyrrolidinyl-1-pentanol·HCl (page 501, compound (10)) and 1-(4-Carbomethoxyphenyl)-2-pyrrolidinyl-1-pentanol·HCl (page 500, compound (9)), which anticipate compounds of the instant claims.

Michaelis et al. is silent as to the stereochemistry of the compounds disclosed, therefore, it is assumed by the examiner that a racemic mixture of each compound is produced in the reference which would result in both the 2-R enantiomer and the 2-S enantiomer of the compounds.

Claims 50-52 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 3,287,217.

Specifically, US Patent No. 3,287,217 discloses the compounds 1-(p-methyl-phenyl)-2-pyrrolidyl-pentanone-(1) (column 3, Example II), 1-(p-chloro-phenyl)-2-pyrrolidyl-pentanone-(1) (column 5, Example VII) and 1-(m-methyl-phenyl)-2-pyrrolidyl-pentanone-(1) (column 5, Example VIII), which anticipate compounds of the instant claims.

US Patent No. 3,287,217 is silent as to the stereochemistry of the compounds disclosed, therefore, it is assumed by the examiner that a racemic mixture of each compound is produced which would result in both the 2-R enantiomer and the 2-S enantiomer of the compounds.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1626

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 7, 11, 16, 50, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 3,287,217.

Determining the scope and contents of the prior art

US Patent No. 3,287,217 discloses the compounds 1-(p-chloro-phenyl)-2-pyrrolidyl-pentanone-(1) (column 5, Example VII) and 1-(m-methyl-phenyl)-2-pyrrolidyl-pentanone-(1) (column 5, Example VIII).

Establishing a prima facie case of obviousness

Different halogens (i.e., fluorine versus chlorine) are considered obvious variants because they are both located in the same seventh group of the periodic system and, thus, have similar properties. *Ex parte Wiseman*, 98 USPQ 277 (1953). Also, positional isomers are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. MPEP §2144.09, *Ex parte Henkel* 130 USPQ 474. *Ex parte Weston*, 121 USPQ 429.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to make the modifications necessary (i.e., to replace the chlorine with fluorine, bromine or iodine and to move the methyl group over to the 2-position on the phenyl) to arrive at compounds of the instant claims with a reasonable expectation of success for obtaining compounds with the same activity. The motivation would have been to make additional compounds which could have been used to stimulate the central nervous system and increase blood pressure.

Art Unit: 1626

Also, as stated above, it is assumed by the examiner that a racemic mixture of each compound is produced in US Patent No. 3,287,217, which would result in both the 2-R enantiomer and the 2-S enantiomer of the compounds.

Thus, a *prima facie* case of obviousness has been established.

Claim Objections

Claims 1-16 and 52 are objected for containing non-elected subject matter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTIN BIANCHI whose telephone number is (571)270-5232. The examiner can normally be reached on Mon-Fri 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kamal A Saeed/

Kristin Bianchi

Application/Control Number: 10/575,177

Page 8

Art Unit: 1626

Primary Examiner, Art Unit 1626

Examiner
Art Unit 1626
